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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/726,730   | 12/03/2003  | Todd Hanson          | HD63/01             | 6338             |
| 49716  | 7590        | 10/05/2005           | EXAMINER            |                  |
| EDWARD P. DUTKIEWICZ, ESQ.<br>EDWARD P. DUTKEIWICZ, P.A.<br>640 DOUGLAS AVENUE<br>DUNEDIN, FL 34698-7001 |             |                      | YUN, JURIE          |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 2882                |                  |

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

|                              |                               |                               |  |
|------------------------------|-------------------------------|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/726,730 | Applicant(s)<br>HANSON ET AL. |  |
|                              | Examiner<br>Jurie Yun         | Art Unit<br>2882              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6 and 9-13 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The amendment filed 7/28/05 has been entered.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the disclosure is not enabling for any and all types of imaging systems and methods such as MRI, ultrasound, PET, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no disclosure of a specific MRI or ultrasound detector that could be used with the probe cylinder.

4. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a "probe" and a "machine alignment tool" and specifically how they are used with the cubic test device. It is unclear what the probe is and what it is used for. The disclosure teaches that it is a radiation detector and should be so claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph. It is unclear what structural limitations are conveyed by "machine alignment tool".

***Claim Objections***

7. Claim 13 is objected to because of the following informalities: the claim appears to recite an additional cubic test device. It is suggested to amend the claim to read, "A medical device standardizing system as described in Claim 2 wherein said cubic test device further comprises scored white central and peripheral grid lines and a ruler,..." Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2, 6, and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliski (USPN 5,511,107) in view of Dawson (USPN 6,364,529 B1).

10. With respect to claim 2, Sliski discloses a medical device standardizing system comprising, in combination, a cubic test device (10) having a centrally located cylindrical aperture (47) there through and a probe cylinder (20) being configured to be received by and held within the central cylindrical aperture.

Sliski does not disclose the aperture from one side to the opposite side.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to do this to allow positioning of the probe anywhere in the test region. Sliski does not disclose a test device resting table having a flat plane surface to receive the cubic test device; a test device resting table level; and a plurality of density

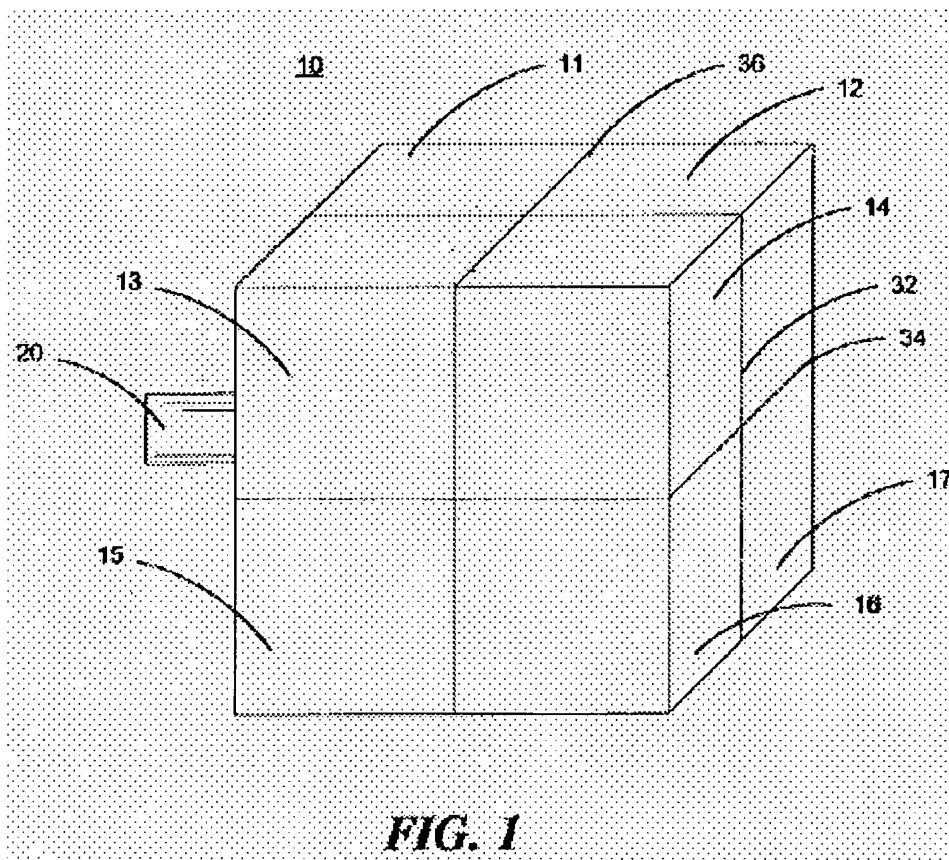
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plugs. Dawson discloses a test device resting table (12) having a flat plane surface to receive the cubic test device (10); a test device resting table level (via 15, 16, 17, and 20 – column 2, lines 53-55); and a plurality of density plugs (column 3, lines 34+). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Sliski to include a test device resting table having a flat plane surface to receive the cubic test device; a test device resting table level; and a plurality of density plugs, as taught by Dawson, to make the Sliski test device more stable and accurate.

11. With respect to claim 9, Sliski discloses the cubic test device further comprises a probe cylinder (20) configured to receive a probe of a radiation detecting and measuring device, the probe being configured and sized to couple within the central cylindrical aperture of the cubic test device.

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12. With respect to claim 6, Sliski discloses the cubic test device (see Fig. 1) has pairs of etched grid lines dividing each face of the cube into four quadrants and four equal squares.



13. With respect to claims 10-13, Sliski does not disclose the resting table comprises a flat plane surface also having a plurality of indicia to enable a user to locate the test cube in the center of the resting table, the resting table having a first central finger configured to couple with a central bore on the bottom face of the cubic test device to prevent the cubic test device from sliding on the resting table, the resting table having a plurality of leveling screws and a recess aperture on one side; a test device level having

a second central finger to couple with the recess aperture of the resting table to hold the resting table in place.

Dawson discloses the resting table (12) comprises a flat plane surface also having a plurality of indicia (see Fig. 1) to enable a user to locate the phantom in the center of the resting table, the resting table having a plurality of leveling screws (15-18 & 20) and a recess aperture on one side.

Dawson does not disclose the resting table having a first central finger configured to couple with a central bore on the bottom face of the cubic test device to prevent the cubic test device from sliding on the resting table, and a test device level having a second central finger to couple with the recess aperture of the resting table to hold the resting table in place. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide these to ensure stability of the test device. Although Dawson does not specifically disclose the elements of claim 12, functional equivalents are taught by Dawson to ensure correct placement of the leveling means. With respect to claim 13, a ruler with indicia for measuring means is well known in the art. And, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the cubic test device scored white central and peripheral grid lines, to provide for better visualization.

#### ***Allowable Subject Matter***

14. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action.

15. Claims 3, 5, and 7-8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

16. Applicant's arguments filed 7/28/05 have been fully considered but they are not persuasive. With regard to applicant's argument that claim 1 has been amended to provide more clarity by amending the claim to include, "a probe cylinder being configured to receive a probe of a radiation detecting and measuring device," it is noted that this does not convey a positive recitation of the probe. The probe itself is not claimed. Therefore, it is not meaningful. Applicants also argue that Sliski and Dawson cannot be combined to form the basis for an obviousness-type rejection for mechanical reasons. Applicants argue that Dawson cannot have an aperture that passes all the way through in that the aperture would then pierce the x-ray films that were held in parallel between the plates. However, Dawson was only relied upon for the teaching of a test device resting table, a test device resting table level, and use of density plugs. Whatever else Dawson shows is not pertinent. For these reasons, the rejection is maintained.

### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jurie Yun whose telephone number is 571 272-2497. The examiner can normally be reached on Monday-Friday 8:30-5:00pm.

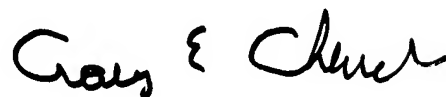
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on 571 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jurie Yun  
September 30, 2005



Craig E. Church  
Primary Examiner